UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

IN RE: Acetaminophen - ASD-ADHD Products Liability Litigation	22md3043 (DLC) 22mc3043 (DLC) 22cv9011 (DLC) 22cv9012 (DLC)
This Document Relates To: Hatfield et al. v. Wal-Mart Stores, Inc., 22cv9011 Roberts et al. v. Wal-Mart Stores, Inc., 22cv9012	MEMORANDUM OPINION AND ORDER

DENISE COTE, District Judge:

On November 14, 2022, motions to dismiss two individual actions in this multidistrict litigation ("MDL") on the ground of preemption were denied. In re Acetaminophen - ASD-ADHD Prods. Liab. Litig., No. 22md3043 (DLC), 2022 WL 17348351 (S.D.N.Y. Nov. 14, 2022) ("November Opinion"). On November 28, the defendant, Walmart Inc. ("Walmart"), filed a motion for reconsideration of the November Opinion and a request for certification under 28 U.S.C. § 1292(b). On December 12, Johnson & Johnson Consumer Inc. ("JJCI"), a co-defendant in this MDL, requested that the Court defer ruling on or, alternatively, deny Walmart's request to certify the November Opinion for interlocutory appeal because JJCI intended to move to dismiss the complaints asserted against it on the ground of preemption.

On February 10, 2023, JJCI and the Retailer Defendants, including Walmart, moved to dismiss all of the complaints

asserted against them on the grounds of preemption and other reasons.[1] On April 20, the Court denied JJCI's motion to dismiss on the ground of preemption. In re Acetaminophen - ASD-ADHD Prods. Liab. Litig., No. 22md3043 (DLC), 2023 WL 3026412 (S.D.N.Y. Apr. 20, 2023).

Walmart's November 28, 2022 motion for reconsideration is denied. The standard for reconsideration is well established and will not be repeated here. See Rodriguez v. Capra, No. 19cv4171 (DLC), 2023 WL 2366884, at *2 (S.D.N.Y. Mar. 6, 2023).

Walmart argues that the November Opinion overlooked the FDA's determination that the general pregnancy warning required for all over-the-counter ("OTC") drugs intended for systemic absorption (the "Pregnancy Warning") was exclusive and preemptive. Not so. The November Opinion described the rulemaking process that led to the regulation containing the Pregnancy Warning, 21 C.F.R. § 201.63 ("Pregnancy Warning Regulation"), and squarely rejected Walmart's argument that the FDA's statements during that process supported preemption. See November Opinion, 2022 WL 17348351, at *9.

Walmart's arguments for reconsideration fail for other reasons as well. Walmart's motion for reconsideration largely

[1] Given the pendency of this motion for reconsideration, Walmart did not move on February 10 to dismiss the two individual actions that were the subject of the November Opinion.

relies on the following statement made by the FDA in the rulemaking process. In response to comments about the Pregnancy Warning Regulation's preemptive effect, the FDA stated:

> [A] single national pregnancy-nursing warning with a specified text is necessary to ensure that OTC drugs are used safely and for their intended purposes. A single national warning will help ensure that consumers receive clear, unambiguous, and consistent information on the labeling of OTC drugs concerning use by pregnant or nursing women. Differing State requirements could conflict with the Federal warning, cause confusion to consumers, and otherwise weaken the Federal warning. FDA believes that differing State OTC drug pregnancy-nursing warning requirements would prevent accomplishment of the full purpose and objectives of the agency in issuing the regulation and that, under the doctrine of implied preemption, these State requirements are preempted by the regulation as a matter of law.

Pregnant or Nursing Women; Delegations of Authority and Organization; Amendment of Labeling Requirements for Over-the-Counter Human Drugs, 47 Fed. Reg. 54750, 54756 (Dec. 3, 1982) (emphasis supplied). Walmart asserts for the first time in its motion for reconsideration that the FDA's interpretation of its regulation as having preemptive power is entitled to deference under Auer v. Robbins, 519 U.S. 452 (1997).

As a preliminary matter, Walmart's argument regarding Auer deference is a new argument and therefore is not entitled to "reconsideration". See Analytical Survs., Inc. v. Tonga Partners, L.P., 684 F.3d 36, 52 (2d Cir. 2012). Putting that aside, the FDA statement about preemption is inapposite.

The FDA's discussion of preemption is not addressed to a manufacturer's duty to ensure that the labels on its drug products are adequate, which is the duty at the heart of this MDL. See Wyeth v. Levine, 555 U.S. 555, 570-71 (2009). The FDA was addressing instead whether States can modify the Pregnancy Warning or replace it with their own version. Here, the plaintiffs are not requesting that the Pregnancy Warning be altered or omitted.

Notably, in making its observation about the doctrine of implied preemption, the FDA did not say that it would be impossible for a manufacturer or retailer to comply with both the Pregnancy Warning Regulation -- which applies to all systemically absorbed OTC drugs and drug products -- and a state law duty to add a warning to their drug labels regarding the risk of the use during pregnancy of a specific drug and any particular health condition. Accordingly, the FDA's statement is largely irrelevant to the plaintiffs' claims.

Walmart's reference to Auer deference is misplaced for another reason as well. When determining whether to defer to an agency's interpretation of its own regulation, a court must first decide, using "all the traditional tools of" statutory interpretation, whether "the regulation is genuinely ambiguous." Kisor v. Wilkie, 139 S. Ct. 2400, 2415 (2019); Walsh v. Walmart, Inc., 49 F.4th 821, 827-28 (2d Cir. 2022). Only if there is

ambiguity may a court inquire into an agency's interpretation of its regulation and apply appropriate deference to that interpretation. Kisor, 139 S. Ct. at 2415.

The Pregnancy Warning Regulation is not ambiguous. It requires use of the Pregnancy Warning as written. See November Opinion, 2022 WL 17348351, at *7. Again, while the Pregnancy Warning itself may not be altered or removed, nothing in the Pregnancy Warning Regulation prevents a manufacturer or retailer from supplementing its label with another pregnancy-related warning. In the absence of ambiguity, there is no need to consider Auer deference.

Given JJCI's December 12 letter request, Walmart's request for certification pursuant 28 U.S.C. § 1292(b) is also denied.

Conclusion

Walmart's November 28, 2022 motion for reconsideration and certification is denied.

Dated: New York, New York
April 27, 2023

DENISE COTE
United States District Judge